510(k) SUMMARY

K102849

This 510(k) Summary provides the following information, in accordance with 21 CFR 807.92.

SUBMITTER'S INFORMATION [21 CFR 807.92(a)(1)]

Radiology Information Systems, Inc. (RADinfo SYSTEMS)
43676 Trade Center Place, Suite 100
Dulles, VA 20166

NOV 2 3 2010

Prepared on September 27, 2010

Contact Person: E.J. Smith
President, Smith Associates (Consultant to Submitter)
1468 Harwell Ave.
Crofton, MD 21114
Phone: 888-729-9674

DEVICE NAME [21 CFR 807.92(a)(2)]

Proprietary Name: AccuImaging
Common Name: AccuImaging
Classification Name: Solid state x-ray imaging system
Regulation Number: 21 CFR 892.1650
Product Code: MQB
Device Class: II

LEGALLY MARKETED PREDICATE DEVICE [21 CFR 807.92(a)(3)]

Company	Trade Name	510(k) Number
Kodak	Eclipse Image Processing Software	K060137

DEVICE DESCRIPTION [21 CFR 807.92(a)(4)]

AccuImaging is a Dynamic Link Library (DLL) module that takes a raw X-ray image generated by a CR or DR as its input and produces a fidelity-quality image for diagnostic purposes. It interfaces with radiological software to analyze digital image data and optimize the processing parameters applied to enhance detail and thus images' diagnostic quality. AccuImaging is not a standalone module and does not implement any user interfaces; it provides a dedicated image processing function to a top-level application running in the Microsoft Windows operating system. It is bound into a parent application that provides user interfaces and dynamically loads the DLL module, forming an integrated process; and, it can also be linked to a service module to provide the image processing service to other top-level applications.

DEVICE INDICATION FOR USE [21 CFR 807.92(a)(5)]

AccuImaging is a software module capable of taking an X-ray image generated by a CR or DR and producing a digitally enhanced image for projection radiography applications. AccuImaging is not indicated for use in mammography.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS [21 CFR 807.92(a)(6)]

The AccuImaging image processing software module is substantially equivalent to the predicate device in both the aspects of the algorithm characteristics and the performance quality, as shown in the table below.

Characteristic	Proposed Device	Predicate Device
Intended use	AccuImaging is a software module capable of taking an X-ray image generated by a CR or DR and producing a digitally enhanced image for projection radiography applications. AccuImaging is not indicated for use in mammography.	The image processing software, used with a cleared CR or DR device, provides diagnostic quality images to aid physicians with diagnosis. This excludes mammography applications.
Materials	Software application	Software application
Where used	Radiology department and medical imaging center	Radiology department and medical imaging center
Technology	Software image processing algorithms enhance the image in both grayscale and K-space.	Software image processing algorithms enhance the image in both grayscale and K-space.
Performance	Performance data was collected. The certification of the equivalence of the performance between the proposed device and the predicate device was provided.	Performance data was collected. The certification of the equivalence of the performance between the proposed device and the predicate device was provided.
Image data source	CR reader or DR	CR reader or DR

Image data format	The input and output image pixel data is the raster data. The photometric representation of the image pixel data is provided.	The input and output image pixel data is the raster data. The photometric representation of the image pixel data is provided.
Operating systems	Microsoft Windows	Microsoft Windows
Noise reduction	The noise reduction is realized with a weighted average of local image pixel values with a profile close to Gaussion distribution. In addition, the mediate value of adjacent pixels is picked up to replace the value of a single-pixel random noise peak.	The Gaussion profile low-pass filter is adopted.
Perceptual Tone Scale (PTS), mapping the linear pixel value to perceptual tone scale.	The image pixel value obtained from an image acquisition instrument is usually related to the input X-ray intensity in a non-logarithmic function, typically a linear or square-root function. This pixel value is mapped to perceptual tone as a logarithmic-like function of the X-ray intensity at the imager detector. The low-intensity wing of the mapping function is modified from the logarithmic function for a recovery from scattered light.	The pixel value is mapped with a logarithmic-like mapping function.
Edge Enhancement	The edge enhancement is realized with a high-frequency band-pass wavelet filter.	Although the detailed algorithm is unknown, the processed image implies that the high-frequency component is enhanced.
Enhanced Visualization	The enhanced visualization processing increases the latitude of the image without	The detailed algorithm is unknown. The processed image indicates that a basic

Processing (EVP)	reducing its contrast, hence reducing the need for the radiologist to manipulate the image. In the EVP, typically the DC component of the image is suppressed while the gradient information of the image is persisted.	DC component suppression algorithm is applied.
Signal-dependent algorithm to optimize localized features and noise reduction	Adaptive algorithms deal with noise reduction and intensity energy leaks.	The noise reduction is enhanced at the low-exposure area.
Type of software program	A dynamic link library module as a part of the image acquisition control program.	A component of the image acquisition control program.

COMPARISON OF DIFFERENCES

Characteristic	Proposed Device	Predicate Device
Indications for Use Statements	AccuImaging is a software module capable of taking an X-ray image generated by a CR or DR and producing a digitally enhanced image for projection radiography applications. AccuImaging is not indicated for use in mammography.	The CR Systems are compact laser scanners capable of reading the latent image formed on a storage phosphor imaging plate and producing a digital image for projection radiography applications. This excludes mammography applications for the Kodak Ektascan Storage Phosphor Reader and the Kodak Eclipse image Processing Software in the United States.

DISCUSSION OF NONCLINICAL TESTS [21 CFR 807.92(b)(1)]

Eight image sets were presented to an expert. The expert was asked to read these images and then answer the following questions:

1. In your professional opinion, do you feel that both sets of images are of diagnostic-quality?
2. In your professional opinion, do you feel that the images' features are equivalent in terms of detail?

The answers provided by the expert's comparative review support substantial equivalence and show that the new device does not introduce questions of safety or effectiveness when compared with the predicate device.

DISCUSSION OF CLINICAL TESTS [21 CFR 807.92(b)(1)]

No clinical testing data is being submitted for this Premarket Notification submission.

CONCLUSION OF PERFORMANCE DATA ASSESSMENTS [21 CFR 807.92(b)(1)]

Based on the above comparisons and the comparative testing between the AccuImaging software module and the predicate device (Section 18) raises no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Radiology Information Systems, Inc.
% Mr. E.J. Smith
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AUG 23 2013

Re: K102849
Trade/Device Name: Acculmaging
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 29, 2010
Received: September 29, 2010

Dear Mr. Smith:

This letter corrects our substantially equivalent letter of November 23, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

NOV 2 3 2010

510(k) Number (if known): K102849

Device Name: **AccuImaging**

Indications for Use:

AccuImaging is a software module capable of taking an X-ray image generated by a CR or DR and producing a digitally enhanced image for projection radiography applications. AccuImaging is not indicated for use in mammography.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ DIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102849